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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/934,970	08/21/2001	Jose L. Boyer	03678.0064.CPUS01	8356

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EXAMINER

LEWIS, PATRICK T

ART UNIT PAPER NUMBER

1623

DATE MAILED: 10/01/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/934,970

Applicant(s)

BOYER ET AL.

Examiner

Patrick T. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 2 and 16-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of Group II in Paper No. 6 dated July 3, 2003 is acknowledged.
2. Claims 2 and 16-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6 dated July 3, 2003.

### *Specification*

3. The Abstract of the Disclosure is objected to because of the use of the word "novel" to describe the compositions of the invention. Applicant is reminded of the proper content of an Abstract of the Disclosure. The Abstract should not refer to the purported merits or speculative applications of the invention and should not compare the invention with the prior art. Where applicable, the Abstract should include the following: if a chemical compound, its identity and use. Appropriate correction is required. See M.P.E.P. § 608.01(b).

### *Double Patenting*

4. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re*

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*Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

5. Claims 1, 4, 5, and 13 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 3, 5, 16, and 6 of copending Application No. 09/643,138. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 3, 6-12, and 14-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4, 16, 26, 30-34, 7-15, and 11 of copending Application No. 09/643,138. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 3, 6-12, and 15 differs from the '138 application in that the '138 application does not set forth the chemical structure of general formula I in the claims;

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however, the '138 application sets forth the chemical structure and variables on pages 6-7 of the specification.

Claim 14 differs from the '138 application in that the '138 application does not recite modes of administration in a single claim.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 1 and 3-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Yerxa et al. U.S. Patent 6,323,187 (Yerxa); Kim et al. *Journal of Biological Chemistry* (1994), Vol. 269, pages 6471-6477 (Kim); and Markland et al. U.S. Patent 5,814,609 (Markland).

Claims 1 and 3-15 are drawn to a method of preventing or treating diseases or conditions associated with platelet aggregation comprising administering to a subject a pharmaceutical composition comprising a therapeutic effective amount of P2Y<sub>12</sub> receptor antagonist compound, wherein said amount is effective to bind P2Y<sub>12</sub> receptors on platelets and inhibit ADR-induced platelet aggregation. Claim 3 limits the P2Y<sub>12</sub> receptor antagonist to a dinucleotide compound of Formula I. Claims 4-7 limit the conditions or diseases treated or prevented. Claims 8-12 limit the method by requiring the administration of a fibrinolytic agent. Claims 13-15 are drawn to systemic administration.

Yerxa teaches the tetraphosphate compounds of the invention when "A" is equal to a nucleoside residue (column 3, lines 15-50). Yerxa also teaches that these compounds are therapeutic compounds that are selective agonists of the P2Y<sub>2</sub> and/or

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P2Y4 purinergic receptor. Yerza however does not teach all of the diseases associated with the treatment of platelet aggregation nor does Yerza teach the administration of a fibrinolytic agent.

Kim teaches that those agonists of P2Y2 and/or P2Y4 purinergic receptors inhibit or modulate platelet aggregation which adequately bridges the nexus between the prior art and the invention as claimed. Markland teaches compositions for the prevention of thrombus formation comprising contortrostatin (CN) and at least one thrombolytic agent (column 12, lines 6-32). Suitable thrombolytic agents include anisoylated plasminogen streptokinase activator complex (APSAC); tissue-type plasminogen activator (tPA); urokinase-type plasminogen activator (uPA); and fibrolase, a snake venom fibrinolytic agent.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to use the compounds of the invention to treat various diseases associated with platelet aggregation. A person of ordinary skill in the art would have been motivated to use these compounds to treat platelet aggregation given the recognition in the prior art that the compounds are selective agonists of the P2Y2 and/or P2Y4 purinergic receptor wherein inhibition of platelet aggregation is conferred through these receptor agonists. Furthermore, the use of materials in combination, each of which is known to function for intended purpose (i.e. inhibition of platelet aggregation), is *prima facie* obvious.

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**Conclusion**

12. Claims 1-21 are pending. Claims 2 and 16-21 are withdrawn from consideration as being drawn to a nonelected invention. Claims 1 and 3-15 are rejected. No claims are allowed.

**Contacts**

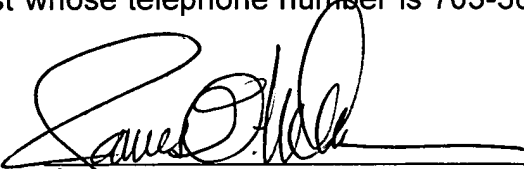
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 703-305-4043. The examiner can normally be reached on M-F 10:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Patrick T. Lewis, PhD  
Examiner  
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ptl



James O. Wilson  
Supervisory Patent Examiner  
Technology Center 1600